

Amendments to the Specification

1. Please replace the paragraphs on page 4, lines 13-18, with the following amended paragraphs:

~~Fig. 7 is a list of therapy substances;~~

~~Fig. 8 is a list of electrically conductive material for use in a gel, or in a microsphere;~~

~~Fig. 9 is a list of binding/gelling agents;~~

~~Fig. 10 lists image contrast agents;~~

~~Fig. 11~~ 7 illustrates components of a microsphere; and

~~Fig. 12~~ 8 is a flow chart of the method of the present invention.

2. Please replace the paragraph at page 8, line 24 to page 9, line 5, with the following amended paragraph:

A list of various treatment substances is given in ~~Fig. 7~~ Table 1. A gel or liquid can contain any combination of these or other treatment substances as required and can be used directly as a gel or liquid, or can be enclosed in microspheres. Some of the representative substances can have dual purposes. For example, saline solution and acetic acid are electrically conductive and are therefore also included under the list of conductive substances in ~~Fig. 8~~ Table 2. A list of binding/ gelling agents is shown in ~~Fig. 9~~ Table 3, and contrast agents are listed in ~~Fig. 10~~ Table 4. A contrast agent is a substance that enhances an image. Numerous agents for enhancing an ultrasound image, for example, are well known to those skilled in the art of imaging, and include dyes and various other substances such as barium sulfate, etc. Including a contrast agent in the gel or microspheres enhances the image.

3. Please replace the paragraph on page 9, lines 6-21, with the following amended paragraph:

The construction of a microsphere 140 as a substance for use in the present invention is more clearly illustrated in reference to Fig. 7 44. A sealed container 142 is shown in cross section, and can have any shape i.e. oval, cylindrical, etc., and with its contents will be referred to generally as a microsphere. The purpose of the microsphere 140 is to carry a substance 144 to a target tissue, and through gradual absorption/disintegration of the container 142, will provide a corresponding gradual release of the treatment substance 144. The microsphere 140 also does not migrate/diffuse as rapidly as a liquid, and therefore allows more control of the area/volume of tissue being treated. The substance 144 can be a gel 146 with elements selected as discussed in reference to ~~Figs. 6-9~~ Fig. 6 and Tables 1-3, or it can be a liquid 148 with similar components including a treatment substance 150 and as required/desired a conductive material 152 and/or a contrast agent 154. The microsphere 140 also preferably contains a gas 156 which can be any of various gasses, such as air, helium, fluorocarbons, etc. as noted in block 158. The microsphere container 142 and contents 144 and 156 are formed by combining a biomaterial or biodegradable polymer 160 (for forming the wall 142) with the substance 144 along with the gas 156 in a pressurized form. The details of such a process are well known to those skilled in the art and need not be described in detail herein.

4. Please add the following tables to page 9, after line 21, as follows:

TABLE 1

THERAPY SUBSTANCES

- **NECROSSING AGENTS**
 - ETHANOL ALCOHOL (1% TO 100% PURE)**
 - SALINE SOLUTION (0.9% TO 99%)**
 - ACETIC ACID (1% TO 100%)**
 - NATURAL EXTRACTS / COMPOUNDS**
 - ENZYMES**
- **ANESTHETIC AGENTS**
 - LIDOCAINE**

MARKAINE
SENSORCAINE

- **ANTIBIOTICS**
- **GENES**
- **VIRUS**
- **VACCINES**
- **PROTEINS**
- **TUMOR SUPPRESSION GENES**
- **INHIBITORS**
- **TISSUE MARKERS**
- **OTHER BIOLOGICAL AGENTS**
- **BIOABSORBABLE POLYMERS**
- **POLYMERS WITH CHEMOTHERAPEUTIC AGENTS
AND PHARMACEUTICAL DRUGS**

TABLE 2

ELECTRICALLY CONDUCTIVE MATERIAL

- **SALINE SOLUTION (ISOTONIC OR HYPERTONIC)**
- **ACETIC ACID**
- **ETHANOL**
- **OTHER, ETC.**
- **CONDUCTIVE POLYMER**
- **METALLIC SUSPENSION**
- **CARBON PARTICLE**
- **CONDUCTIVE ELEMENT**

TABLE 3

BINDING/GELLING AGENTS

1. **Polymers**
 - i) **hydroxyl propyl cellulose**
 - ii) **hydroxyl propyl methyl cellulose**
 - iii) **hydroxyl propyl ethyl cellulose**
 - iv) **poly vinyl alcohol**
2. **Biodegradable polymer**
3. **Bio-material**
4. **Oil and Animal Fat Based Biomaterial and Agents**

5. Collagen-Natural Derivatives and Synthetic Formulations
6. Phase Changing Gelling Agents
7. Energy Activated Gelling Agents
8. Proteins, Conjugates and Tissue Cell Compositions

TABLE 4

CONTRAST AGENT

- **DYE**
- **BARIUM SULFATE**
- **OTHER**

5. Please replace the paragraph at page 9, line 27, to page 9, line 12, with the following amended paragraph:

The preferred method of the present invention will now be described in reference to the flow chart of Fig. 8 +2. A hollow core needle, or probe and hollow core needle or catheter is/are inserted into a patient's body (block 162) through an appropriate opening, such as an incision, or through a natural passageway such as a urethra or cervical canal, rectum, etc. If a catheter or probe is used, the hollow core needle can be inserted through the probe or catheter either before or after insertion of the probe or catheter in the body. Through use of an endoscope, and/or a non-invasive detection positioning and imaging method, for example using ultrasound, etc., the user accurately positions the needle near a site to be treated (block 164). Having arrived near the target area, either an endoscope and/or non-invasive detection and imaging methods such as X-RAY, CT SCAN, MRI, ultrasound, fluoroscopy, etc. can be used to guide the needle or an appropriate needle assembly to a target area to be treated, and to monitor injection of the treatment substance. The needle assembly can be solely for application or injection of a substance to a precise target tissue location, or it can be additionally for application of RF energy.

6. Please replace the paragraph on page 12, lines 11-15, with the following amended paragraph:

In applications for destruction/death of tissue, the necrossing agent can be combined with carrier agents and/or an anesthetic agent and/or with an antibiotic. Anesthetic agents,

for example, include Lidocaine, Markaine and Sensorcaine as listed in Table 1 Fig-7, and other anesthetic agents known by those skilled in the art. Similarly, antibiotic agents include the various products known in the art.

7. Please replace the paragraph on page 12, lines 16-28, with the following amended paragraph:

The method of the present invention also has a significant advantage in gene therapy. In this case the application of RF energy for causing tissue death is generally not applicable. However, a smaller amount of RF energy can be applied for the purpose of raising the tissue temperature, i.e. creating hyperthermia to enhance a process. The prior art method of gene delivery injects genes into the body intravenously or intra-arterially using a conventional needle. This distributes the genes throughout the body. Ideally, the genes should be confined to the target area. Genes are listed in Table 1 Fig-7, as are other substances that for many illnesses, such as the treatment of tumors, should optimally be injected directly into the tumor or other target tissue. These include viruses, vaccines, proteins, tumor suppression genes, inhibitors, markers, and other biological agents. The substances that can be used in accordance with the therapy of the present invention also include mixtures of the above listed items and other chemicals, agents and their solutions in the form of gel, or suspensions, liquids or semi-liquids in microspheres that will be understood by those skilled in the art.

8. Please replace the paragraph on page 13, lines 1-11, with the following amended paragraph:

The method of Fig. 8 42 according to the present invention is meant to cover treatment of any body part. A most important embodiment is the method of the present invention applied to causing selective tissue necrosis, with or without the application of RF energy. Preferred embodiments of the present invention include treatment of the prostate, kidney, uterine myoma, fibroids, liver, ovarian cancer, bladder cancer, breast tumors and cysts (benign or malignant), and stomach, lung, colon and brain cancer, etc., and in the procedure of endometrial ablation of the uterine lining. An important embodiment in use with male patients is treatment of BPH (benign Prostatic Hyperplasia), enlarged prostate growth and prostate cancer. In this case, the needle can be inserted transurethral, transrectal, or transperineal with or without an incision. The probe can also be inserted

transperineally or transrectally (through the rectum) with or without incision under imaging guidance.